

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hungerford et al *
Serial No. (to be assigned) *
Filed: (concurrently herewith) * Art Unit: (to be assigned)
For: CELL-CULTURE AND * Examiner: (to be assigned)
POLYMER CONSTRUCTS *

PRELIMINARY AMENDMENT

To the Honorable Commissioner
of Patents and Trademarks
Washington, DC 20231

Dear Sir:

In the Specification

Specification page 2 under related applications, cancel lines 4 and 5 and substitute the following paragraph submitted in clean-form on the following sheet.

Docket No. 21418-PA-DIV
Inventors: Hungerford et al

The application is related to provisional applications Serial No. 60/081,016 filed April 8, 1998 and Serial No. 60/104,842 filed October 20, 1998; and is a divisional application of Serial No. 09/275,319 filed March 24, 1999, now U. S Patent _____.

Docket No. 21418-PA-DIV
Inventors: Hungerford et al

IN THE CLAIMS:

Please add new claims 36 - 83 presented in clean form on the following pages.

36. A method of repairing a diseased or injured tissue in a patient, comprising the steps of surgically obtaining a healthy chondrocyte specimen from a different part of the patient's body, rapidly growing high-quality chondrocytes externally of the patient's body in spin-culture on microcarrier particles, and surgically implanting the rapidly grown high-quality chondrocytes into the diseased or injured tissue of the patient, such that the high-quality chondrocytes regenerate within the patient's body, thereby producing a long-term cure of the patient's diseased or injured tissue.

37. The method of claim 36, wherein the healthy chondrocyte specimen is conveniently taken from the patient's nasal septal cartilage.

38. The method of claim 36, wherein the rapidly grown high-quality chondrocytes are implanted for orthopedic purposes.

39. The method of claim 38, wherein the implantation is in the patient's knee.

40. The method of claim 36, wherein the high-quality chondrocytes are grown in spin-culture on microcarrier particles in a reduced oxygen environment.

41. The method of claim 40 in which the low oxygen environment contains about 5% oxygen.

42. The method of claim 36, wherein the microcarrier particles are composed of a biodegradable and biocompatible material.

43. The method of claim 42, wherein the biodegradable and biocompatible material is selected from a group consisting of collagen, collagen-coated biopolymers, dextran,

N,N-diethylaminoethyl (DEAE)-dextran, or N,N,N-trimethyl-2-hydroxy-aminopropyl-dextran.

44. The method of claim 42, wherein the biodegradable and biocompatible material is a cross-linked polymer prepared by crosslinking a polysaccharide with a polyamine.
45. The method of claim 44, wherein the polysaccharide is selected from the group consisting of dextran, arabinogalactan, pollulan, cellulose and amylose.
46. The method of claim 44, wherein the crosslinking polyamine is selected from a group consisting of lysine, ethylenediamine, alkylenediamine, phenylenediamine, xylenediamine, polyethylenimine, gelatin, albumin and fibrinogen.
47. A method of repairing a diseased or injured tissue in a patient, comprising the steps of surgically obtaining a healthy chondrocyte specimen from a different part of the patient's body, rapidly growing high-quality chondrocytes externally of the patient's body in a low-oxygen environment, and surgically implanting the rapidly grown high-quality chondrocytes into the diseased or injured tissue of the patient, such that the high-quality chondrocytes regenerate within the patient's body, thereby producing a long-term cure of the patient's diseased or injured tissue.
48. The method of claim 47 in which the low oxygen environment contains about 5% oxygen.
49. The method of claim 47, wherein the healthy chondrocyte specimen is conveniently taken from the patient's nasal septal cartilage.

50. The method of claim 47, wherein the rapidly grown high-quality chondrocytes are implanted for orthopedic purposes.

51. The method of claim 50, wherein the implantation is in the patient's knee.

52. The method of claim 47, wherein the high-quality chondrocytes are grown in a low oxygen environment in spin-culture on microcarrier particles.

53. The method of claim 52, wherein the microcarrier particles are composed of a biodegradable and biocompatible material.

54. The method of claim 53, wherein the biodegradable and biocompatible material is selected from a group consisting of collagen, collagen-coated biopolymers, dextran, N,N-diethylaminoethyl(DEAE)-dextran, or N,N,N-trimethyl-2-hydroxy-aminopropyl-dextran.

55. The method of claim 53, wherein the biodegradable and biocompatible material is a cross-linked polymer prepared by crosslinking a polysaccharide with a polyamine.

56. The method of claim 55, wherein the polysaccharide is selected from the group consisting of dextran, arabinogalactan, pollulan, cellulose and amylose.

57. The method of claim 55, wherein the crosslinking polyamine is selected from a group consisting of lysine, ethylenediamine, alkylenediamine, phenylenediamine, xylenediamine, polyethylenimine, gelatin, albumin and fibrinogen.

58. A method of repairing a diseased or injured tissue in a patient, comprising the steps of surgically obtaining a healthy tissue specimen from a different part of the patient's body, rapidly growing high-quality cells from the tissue specimen externally of the

patient's body in spin-culture on microcarrier particles, and surgically implanting the rapidly grown high-quality cells into the diseased or injured tissue of the patient, such that the high-quality cells regenerate within the patient's body, thereby producing a long-term cure of the patient's diseased or injured tissue.

59. The method of claim 58, wherein the healthy tissue specimen is conveniently taken from the patient's bone marrow, periosteum, perichondrium, cartilage, bone, or peripheral blood.
60. The method of claim 58, wherein the healthy tissue specimen is conveniently taken from the patient's bone marrow.
61. The method of claim 58, wherein the cells are selected from a group consisting of chondrocytes, osteoblasts, osteocytes, chondrogenic cells, pluripotential cells, progenitor mesenchymal cells, fibroblasts, and mucosal cells.
62. The method of claim 58, wherein the rapidly grown high-quality cells are implanted for orthopedic purposes.
63. The method of claim 62, wherein the implantation is in the patient's knee.
64. The method of claim 58, wherein the high-quality cells are grown by spin-culture on microcarrier particles in a reduced oxygen environment.
65. The method of claim 64 in which the low oxygen environment contains about 5% oxygen.
66. The method of claim 58, wherein the microcarrier particles are composed of a biodegradable and biocompatible material.

67. The method of claim 66, wherein the biodegradable and biocompatible material is selected from collagen, collagen-coated biopolymers, dextran, N,N-diethylaminoethyl(DEAE)-dextran, or N,N,N-trimethyl-2-hydroxy-aminopropyl-dextran.

68. The method of claim 66, wherein the biodegradable and biocompatible material is a cross-linked polymer prepared by crosslinking a polysaccharide with a polyamine.

69. The method of claim 68, wherein the polysaccharide is selected from the group consisting of dextran, arabinogalactan, pollulan, cellulose and amylose.

70. The method of claim 68, wherein the crosslinking polyamine is selected from a group consisting of lysine, ethylenediamine, alkylenediamine, phenylenediamine, xylenediamine, polyethylenimine, gelatin, albumin and fibrinogen.

71. A method of repairing a diseased or injured tissue in a patient, comprising the steps of surgically obtaining a healthy tissue specimen from a different part of the patient's body, rapidly growing high-quality cells externally of the patient's body in a low-oxygen environment, and surgically implanting the rapidly-grown high-quality cells into the diseased or injured tissue of the patient, such that the high-quality cells regenerate within the patient's body, thereby producing a long-term cure of the patient's diseased or injured tissue.

72. The method of claim 71 in which the low oxygen environment contains about 5% oxygen.

73. The method of claim 71, wherein the healthy tissue specimen is conveniently taken from the patient's bone marrow, periosteum, perichondrium, cartilage, bone, or peripheral blood.
74. The method of claim 71, wherein the healthy tissue specimen is conveniently taken from the patient's bone marrow.
75. The method of claim 71, wherein the cells are selected from a group consisting of chondrocytes, osteoblasts, osteocytes, chondrogenic cells, pluripotential cells, progenitor mesenchymal cells, fibroblasts, and mucosal cells.
76. The method of claim 71, wherein the rapidly grown high-quality cells are implanted for orthopedic purposes.
77. The method of claim 76, wherein the implantation is in the patient's knee.
78. The method of claim 71, wherein the high-quality cells are grown by spin-culture on microcarrier particles.
79. The method of claim 78, wherein the microcarrier particles are composed of a biodegradable and biocompatible material.
80. The method of claim 79, wherein the biodegradable and biocompatible material is selected from a group consisting of collagen, collagen-coated biopolymers, dextran, N,N-diethylaminoethyl(DEAE)-dextran, or N,N,N-trimethyl-2-hydroxy-aminopropyl-dextran.
81. The method of claim 79, wherein the biodegradable and biocompatible material is a cross-linked polymer prepared by crosslinking a polysaccharide with a polyamine.

82. The method of claim 81, wherein the polysaccharide is selected from the group consisting of dextran, arabinogalactan, pollulan, cellulose and amylose.
83. The method of claim 81, wherein the crosslinking polyamine is selected from a group consisting of lysine, ethylenediamine, alkylenediamine, phenylenediamine, xylenediamine, polyethylenimine, gelatin, albumin and fibrinogen.

Summary

Included in the Preliminary Amendment are continuing data and additional claims.

Respectfully submitted,

Date

January 3, 2002

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